

I. AMENDMENTS

Amendments to the Specification

Please delete the section entitled "Related Application" in its entirety, and replace it with the following new section:

- - Cross Reference to Related Applications

This application is a continuation of patent application U.S. Serial No. 09/298,358, filed on April 23, 1999, which claims priority to provisional patent application U.S. Serial No. 60/082,786 filed on April 23, 1998. The subject matter of this application is also related to patent application U.S. Serial No. 08/512,844, filed on August 9, 1995; patent application U.S. Serial No. 08/703,479, which published as PCT 98/09167 on March 5, 1998; and patent application U.S. Serial No. 08/642,228, which published as PCT 97/41421 on November 6, 1997. All such patents and applications are incorporated herein by reference in their entirety.- -

Amendments to the Claims

Please cancel claim 1. Please add new claims 2 to 38. The Listing of the Claims that follows will replace all prior versions, and listings, of claims in the application:

Listing of the Claims

2. (New) A dry reagent lateral flow strip assay device for detecting two or more analytes in a test sample comprising:

- a) a sample application zone; and
- b) two or more test zones;

wherein the sample application zone and the two or more test zones are in fluid communication with one another through a transport matrix; and
wherein the transport matrix further comprises a lateral path along which the sample travels laterally, and a transverse path along which the sample travels transversely.

3. (New) The assay device of claim 2 for performing general chemistry assays, wherein the two or more test zones are general chemistry reagent zones comprising at least one enzyme.

4. (New) The assay device of claim 2, wherein the two or more analytes are general chemistry analytes selected from the group consisting of: creatine, creatinine, glucose, cholesterol, high density lipoprotein (HDL) cholesterol, N-telopeptide, low density lipoprotein (LDL) cholesterol, triglycerides and blood urea nitrogen (BUN).

5. (New) The assay device of claim 2, wherein the general chemistry reagent zone further comprises an indicator.

6. (New) The assay device of claim 2 for performing a binding assay, wherein the two or more test zones are binding member zones comprising at least one binding member.

7. (New) The assay device of claim 6, wherein the binding member is an antibody.

8. (New) The assay device of claim 2, wherein the two or more analytes are selected from the group consisting of: antigens, antibodies, macromolecules, vitamins, lectins, carbohydrates, proteins, peptides, amino acids, hormones, steroids, therapeutic drugs, drugs of abuse, bacterium and viruses.

9. (New) The assay device of claim 2, wherein the two or more analytes are haptens that form binding pairs with antibodies.

10. (New) The assay device of claim 7, wherein the antibody is immobilized in the binding member zone.

11. (New) The assay device of claim 10, wherein the antibody is diffusively immobilized in the binding member zone.

12. (New) The assay device of claim 10, wherein the antibody is non-diffusively immobilized in the binding member zone.

13. (New) The assay device of claim 2, wherein the sample application zone further comprises a sample pad in fluid communication with the transport matrix.

14.(New) The assay device of claim 13, further comprising a sample treatment pad in fluid communication with the transport matrix.

15. (New) The assay device of claim 14, wherein the sample treatment pad comprises a quaternary ammonium derived membrane for trapping ascorbate and other anionic interferents.

16. (New) The assay device of claim 13, further comprising a sample filter pad in fluid communication with the transport matrix for removing undesired contaminants from the sample.

17. (New) The assay device of claim 13, wherein the sample pad removes large particulate debris from the sample.

18. (New) The assay device of claim 13, wherein the sample pad adjusts the pH and ionic composition of the sample.

19. (New) The assay device of claim 2, wherein the transport matrix is a porous material along which the sample travels laterally.

20. (New) The assay device of claim 2, further comprising a metering layer between the transport matrix and the two or more test zones through which the sample spreads uniformly across the transport matrix.

21. (New) The assay device of claim 3, wherein the enzyme produces a reaction product when at least one of the analytes is present in the sample.

22. (New) The assay device of claim 6, wherein at least one of the binding members forms a complex with at least one analyte.

23. (New) The assay device of claim 5, wherein the indicator forms a detectable signal when at least one of the analytes is present in the sample.

24. (New) The assay device of claim 6, wherein at least one of the binding member zones further comprises an indicator that forms a detectable signal when at least one of the analytes is present in the sample.

25. (New) The assay device of claim 2, further comprising a detection zone corresponding to each test zone.

26. (New) A dry reagent lateral flow strip assay device for detecting two or more analytes in a test sample comprising:

- a) a sample application zone;
- b) a general chemistry reagent zone comprising at least one enzyme; and
- c) a binding member zone comprising at least one binding member;

wherein the sample application zone, the general chemistry reagent zone and the binding member zone are in fluid communication with one another through a transport matrix.

27. (New) A diagnostic device for performing a dry reagent lateral flow assay on a strip comprising:

- a) a housing;
- b) a cover for the housing having an interior surface and an exterior surface, wherein a sample receptor extends therethrough;
- c) a sample pad;
- d) at least one assay strip in fluid communication with the sample pad, wherein the assay strip comprises at least two test zones; and

e) a reflectometer enclosed in the housing adapted to transmit results from the assay.

28. (New) The device of claim 27, wherein the sample receiving device further comprises a sample filter pad.

29. (New) The device of claim 27, wherein the sample receiving device removes undesired contaminants from the sample.

30. (New) The device of claim 27, wherein the assay strip further comprises at least one sample filter pad.

31. (New) The device of claim 27, wherein the reflectometer further comprises a printed writing assembly having a printed circuit board.

32. (New) The device of claim 27, wherein the reflectometer further comprises an optics assembly.

33. (New) The device of claim 31, wherein the printed circuit board has a face with at least two zone detectors mounted directly thereto.

34. (New) The device of claim 32, wherein the optics assembly is configured to translate reflected signal from the test zones into a reflectance reading.

35. (New) A method for detecting two or more analytes in a test sample using a dry reagent lateral flow strip assay device, comprising the steps of:

a) preparing an assay device comprising a sample application zone and two or more test zones in fluid communication with one another through a transport matrix, wherein the transport matrix further comprises a lateral path along which the sample travels laterally, and a transverse path along which the sample travels transversely;

b) applying a sample to the sample application zone;

c) permitting the sample to flow along the lateral path and the transverse path;

and

d) detecting a signal from the test zones.

36. (New) The method of claim 35, wherein the test sample is derived from whole blood, whole blood components, ascites, urine, sweat, milk, synovial fluid, peritoneal fluid, amniotic fluid or cerebrospinal fluid.

37. (New) The method of claim 35, wherein the sample is pretreated prior to application.

38. (New) A system for detecting two or more analytes in a test sample comprising:

a) a dry reagent lateral flow strip assay device, wherein the strip assay device comprises:

- i) a sample application zone; and
- ii) two or more test zones;

wherein the sample application zone and the two or more test zones are in fluid communication with one another through a transport matrix; and

b) the diagnostic device of claim 27.